UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/495,556 | 02/01/00 | KUHRTS | E |

HM22/1208

Eric H Kuhrts
P O Box 387
1109 Tannery Creek Rd
Bodega CA 94922

| EXAMINER | |
|---|---|
| DI NOLA BARON,L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | 3 |

**DATE MAILED:** 12/08/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/495,556 | KUHRTS, ERIC H. | |
| | Examiner | Art Unit | |
| | Liliana Di Nola-Baron | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 September 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 8, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The claimed invention refers to a process for producing sustained-release particles, comprising dispersing a core material in a mixer while adding an oil, and to a sustained-release pharmaceutical composition, comprising a therapeutic agent and an oil.

5. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. Miller et al. discloses a process for manufacturing sustained release particles and dosage forms obtained by processing said particles (See e.g., col. 1, lines 8-15). Miller et al. teaches that the process of the invention comprises working in a high-speed mixer a mixture of a drug, a carrier having a melting point between 35° and 150° C and optionally a release control component, at a

speed and energy input, which allows the carrier to melt or soften, and breaking down the agglomerates (See e.g., col. 1, lines 48-67 and Examples 1-4). Miller et al. teaches that the drug may be water soluble or water insoluble and includes analgesics, such as acetyl salicylic acid, antiallergics, antihypertensives, antibiotics and others among the active ingredients, which can be used in the process of the invention (See e.g., col. 2, line 11 to col. 3, line 28). Miller et al. teaches that preferably all the drug is added, together with the carrier, in the first step, which may be carried out in conventional high speed mixers at temperatures above 40° C (See e.g., col. 3, line 54 to col. 4, line 6). Miller et al. teaches that the agglomerates formed upon heating are allowed to cool and then broken down (See e.g., col. 4, lines 11-25). Miller et al. teaches that the energy in the high speed mixer can be delivered by a heating jacket and the resulting particles may be used to prepare dosage units, such as tablets or capsules (See e.g., col. 4, lines 41-51). Miller et al. teaches that suitable hydrophobic carriers are natural or synthetic waxes or oils, such as hydrogenated vegetable oil, having melting points of 35° –150° C (See e.g., col. 5, lines 15-20). Additionally, Miller et al. teaches that optionally added release control components may be inorganic and organic materials, including calcium and lactose (See e.g., col. 5, lines 27-34). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process and compositions disclosed by Miller et al., by varying the amount of oil, sugar or mineral in the melt. One of ordinary skill in the art would have been motivated to make such modifications to obtain different sustained-release profiles. Because of the teachings of Miller et al., that suitable selection of the materials used in forming the particles and the proportions in which they are used enables a significant degree of control in the dissolution and release rate, one of ordinary skill in the art would have a reasonable

expectation that the process and compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

6. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al.

Oshlack et al. provides sustained-release pharmaceutical formulations and methods for preparing the same (See e.g., col. 3, line 40 to col. 5, line 9). Oshlack et al. teaches that the therapeutic agent of the invention is incorporated into a melt-extruded strand and mixed with a hydrophobic carrier (See e.g., col. 6, lines 23-40 and col. 13, lines 24-54). Oshlack et al. teaches that the therapeutic agents, which may be used in the invention, include water soluble and water insoluble drugs, such as antihistamines, analgesics (aspirin) and vitamins (See e.g., col. 6, line 50 to col. 7, line 39). Oshlack et al. teaches that preferred hydrophobic materials to be used in the invention include hydrogenated vegetable oil and any hydrophobic material, which imparts sustained release of the active agents and melts (See e.g., col. 8, lines 36-51). Oshlack et al. explains that the hydrophobic carrier is preferably water insoluble and has a melting point between 30° and 200° C (See e.g., col. 9, lines 11-39). Oshlack et al. teaches that the matrix may also contain other materials, such as diluents, lubricants and binders (See e.g., col. 9, lines 40-56). Oshlack et al. teaches that the analgesic of the invention is mixed with one hydrophobic material and a retardant material to obtain a homogenous mixture, which is heated to a temperature sufficient to soften the mixture and extrude it, and the extrudate is cooled and cut into multiparticulates (See e.g., col. 9, line 57 to col. 10, line 22). Oshlack et al. teaches that the

oral dosage forms are prepared to include an effective amount of the multiparticulates (See e.g., col. 10, lines 49-55). Oshlack et al. teaches that the typical melt extrusion system used in the invention includes temperature sensors and cooling means and a tween-screw extruder (See e.g., col. 12, lines 35-57).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process and compositions disclosed by Oshlack et al., by varying the composition and amount of oil, sugar or mineral in the melt. One of ordinary skill in the art would have been motivated to make such modifications to obtain different sustained-release profiles. Because of the teachings of Oshlack et al., that pharmaceutically acceptable excipients may be incorporated in the melt-extruded multiparticulates of the invention up to 50% by weight of the particulate, one of ordinary skill in the art would have a reasonable expectation that the process and compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Friday, 6:30AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

December 7, 2000

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600